Message

From: Watkins, Tim [Watkins.Tim@epa.gov]
Sent: 9/7/2017 9:40:42 PM
To: ORD-NERL Feds [ORDNERL_Feds@epa.gov]
Subject: Managing Samples across NERL Laboratories

NERL Scientists,

As we go through the steps for improved laboratory utilization here in RTP and as researchers in Las Vegas and Athens prepare to move out of their current facilities, the issue of "can and should I dispose of my old samples?" has arisen. There are 4 basic points that need to be addressed to ensure we are not disposing of "records" nor are we keeping samples indefinitely.

1) **From the Records Management view point**:

Schedule 1035 does say under its guidance that Tissue samples and specimens, including wet specimens, samples of test, control, or reference substances, and specially prepared material that are relatively fragile and differ markedly in stability and quality during storage, are to be retained only as long as the quality of the preparation affords evaluation. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, biological fluids, do not need to be retained after quality assurance verification. In some research studies involving humans, the agreement with the human subjects requires samples to be destroyed immediately after the analysis and quality assurance verification is complete. In that case, the sample is retained as specified in the agreement. **Other tissue samples and specimens are to be retained according to the disposition instructions for item d.** [Here is the website for the records management issue: http://intranet.epa.gov/records/schedule/final/1035.html]

Item d states:

- **Disposable**
- Close when activity, project, or topic completed
- Destroy 5 years after file closure. (this is appropriate for paper records/files)

2) **From a QA view point:**

If the samples are past their holding times or the holding times of like compounds, then the quality of samples is suspect and the samples should be disposed of.

3) **From a liability view point:**

The samples may have degraded during storage. If you reanalyze the samples sometime in the future, you may get a different chemical concentration or microbial response, and you may find degradation products and not the original compounds. The degradants may be more toxic than the parent compound and now that data says there is a hazard when originally there was not a hazard leading to a legal issue of reporting the "new" data. Also, if you keep the samples and reanalysis for other purposes is required, biases may be introduced as they samples were not collected properly for the new purpose.

4) **From the disposal view point:**

As researchers, you know what the samples are now. As time goes by, or if the researcher retires, we tend to forget what the samples are/were, what was in them, the sample identification/numbering schemes tend to get lost, or the labeling on the sample/standard gets removed. Once any of these situations occur, NERL incurs a large cost for the disposal of the unknown samples as they must be disposed of as the most hazardous class of chemicals.

As with everything, there are a few exceptions. If the samples are part of a holding time study (documented through an approved QAPP), then dispose of them when the study is completed. If the samples are under some form of litigation

hold (your records management person can check this out for you although most litigation holds are for the "paper" record not the sample itself), then hold onto them until the litigation hold is lifted. If the sample is just being used as a matrix for further studies (documented through an approved QAPP) in which new methods are being developed (e.g., hydraulic fracturing flowback water for spiking studies in high salt/TDS matrices), then keep them until the study is completed and the data QA verified.

In summary, if the samples are no longer needed or are past their holding times, please dispose of the samples properly. If you have published the results of the study, the data has then been "quality assurance verified" (see schedule 1035), then the samples should be disposed of properly.

Your efforts to assess the status of your samples considering the information above and, when appropriate, to dispose of samples are greatly appreciated, particularly as we work to consolidate our laboratory operations across the organization and to minimize the associated sample shipments and sample storage requirements.

Thank you.

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